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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/785,374	02/16/2001	Anthony M. Looper	VM 6010.2	5023

7590

10/08/2003

ALLEGIANCE CORPORATION  
ATTN: KIM DILIBERTI  
1430 WAUKEGAN ROAD  
MCGAW PARK, IL 60085-6787

EXAMINER
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PATEL, MITAL B

ART UNIT	PAPER NUMBER
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3743

DATE MAILED: 10/08/2003

18

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/785,374

Applicant(s)

LOOPER ET AL

Examiner

Mital B. Patel

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3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 31 July 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3-13,15-24,26-31,33-37,39-43 and 45-89 is/are pending in the application.
- 4a) Of the above claim(s) 22-24,26-31,33-37,39-43 and 45-89 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-13,15-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## DETAILED ACTION

### *Response to Amendment*

1. Applicant's arguments filed 7/31/03 have been fully considered but they are not persuasive.
2. In response to Applicant's remarks regarding the election requirement required in the Office Action mailed 3/20/02, please note that an Election of Species was required rather than a restriction. Applicant requests that Examiner give the basis for the requirement of restriction by identifying how the various embodiments are independent and distinct. This is not found persuasive because, as stated in the Official Action dated March 20, 2002, an Election of Species was required by applicant, not a restriction. As stated in MPEP Section 808.01(a) paragraph one, when there are species of patentable distinction, as shown by examiner in Official Action, paragraph one, they are independent inventions and the election of one invention is mandatory following a requirement for restriction, even though applicant disagrees with the examiner. Furthermore, examiner is required only to clearly identify each species using the figures that apply to each species. In response to applicant's request for examiner to address claims, it is the responsibility of applicant to elect a species and include all the claims readable thereon for a complete, proper election {MPEP 809.02(a)}.
3. In response to Applicant's arguments with respect to Makower being silent to explicitly teaching of a tube that is kink resistant, fatigue resistant and bending about some bending radius, it should be noted that the disclosure in Column 7,

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lines 4-16 teaches that the tube "can be made out of any material appropriate for the nature of its use and in particular a medical grade plastics, metals..." Such a teaching provides sufficient motivation to one of ordinary skill in the art to make a tube as set forth by the Applicant, especially since Makower states that the tube can be made of any material suitable for a particular function. The Applicant contends that Makower teaches the use of ceramics as a material but the use of ceramics as material is inclusive along with medical grade plastics and metals both of which exhibit bending at some bending radius. Makower does not limit the material of the tube to any particular material, ceramics or otherwise. The Examiner maintains the rejection under 35 U.S.C. 103(a).

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1, 3-13, and 15-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Makower et al (US 5474057).

6. **As to claim 1**, Makower teaches a surgical device comprising a tissue engaging means **15,17** and a handle assembly **34**; and an actuating means **19** connecting the handle assembly and the tissue engaging means for actuating the tissue engaging means, a shaft member comprising a first tube **11** made of a

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malleable material and having a proximal end, a distal end and a longitudinal axis, the proximal end of the first tube adapted to be coupled to the handle assembly, the distal end of the first tube adapted to be coupled to the tissue engaging means, the actuating means adapted to extend axially through the first tube, the first tube configured to be kink resistant and fatigue resistant and to bend about some bending radius in response to a bending moment applied to the first tube (**See Col. 7, lines 4-16**). Makower is silent to the specific range of bending moment. However, Applicant has not provided sufficient structure to result in structural differences between the claimed invention and the shaft of Makower and therefore, the shaft member of Makower is fully capable of bending in the range disclosed. Furthermore, it would be obvious to one of ordinary skill to provide a tube with a specific bending moment based on the intended use and function as disclosed by Makower in Col. 7, lines 4-16.

7. **As to claims 3-4**, Makower teaches essentially all of the limitations except for the specific range of the bending moment. However, the Applicant has not provided sufficient language and structure to result in structural differences between the claimed invention and the shaft of Makower, and therefore, the shaft member of Makower is fully capable of bending in the range disclosed.

Furthermore, it would be obvious to one of ordinary skill to provide a tube with a specific bending moment based on the intended use and function as disclosed by Makower in Col. 7, lines 4-16.

8. **As to claims 5 and 7**, Makower teaches essentially all of the limitations except for the specifics of the wall thickness. However, it would be obvious to

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one of ordinary skill in the art to arrive at the particular dimensions depending on what specific medical procedure or surgical procedure the shaft member was required from since different sized tubes are used for different parts of the body when performing a surgical or medical procedure.

9. **As to claim 6**, Makower teaches a shaft member wherein the first tube is made of material selected from the group consisting of stainless steel, copper, aluminum, and brass (**See Col. 7, lines 4-16**).

10. **As to claim 8**, Makower teaches a shaft member wherein the proximal end of the first tube is adapted to be removably coupled to the handle assembly.

11. **As to claim 9**, Makower teaches a shaft member wherein the distal end of the first tube is adapted to be removably coupled to the tissue engaging means.

12. **As to claim 10**, Makower teaches a shaft member further comprising a second tube **24**, the first tube coaxially aligned and disposed within the second tube.

13. **As to claim 11**, Makower teaches a shaft member wherein the second tube is made of material selected from the group consisting of aluminum, brass, copper and plastic.

14. **As to claim 12**, Makower teaches a shaft member wherein the first and second tubes are formed from co-extrusion (**Col. 7, line 10**).

15. **As to claim 13**, Makower teaches a surgical device comprising a tissue engaging means **15** including first and second opposed jaws **17** for grasping, securing, and occluding body tissue and conduits; a handle assembly **34**, and an actuating means **19** connecting the handle assembly and the tissue engaging

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means for actuating the tissue engaging means, a malleable shaft member **11** comprising a first tube made of a malleable material and having a proximal end, a distal end and a longitudinal axis, the proximal end of the first tube coupled to the handle assembly, the distal end of the first tube coupled to the tissue engaging means, the actuating means extending axially through the first tube, the first tube configured to be kink resistant and fatigue resistant and to bend about some bending radius in response to a bending moment applied to the first tube (**See Col. 7, lines 4-16**). Makower is silent to the specific range of bending moment. However, Applicant has not provided sufficient structure to result in structural differences between the claimed invention and the shaft of Makower and therefore, the shaft member of Makower is fully capable of bending in the range disclosed. Furthermore, it would be obvious to one of ordinary skill to provide a tube with a specific bending moment based on the intended use and function as disclosed by Makower in Col. 7, lines 4-16.

16. **As to claim 15**, Makower teaches essentially all of the limitations except for the specific range of the bending moment. However, the Applicant has not provided sufficient language and structure to result in structural differences between the claimed invention and the shaft of Makower, and therefore, the shaft member of Makower is fully capable of bending in the range disclosed.

Furthermore, it would be obvious to one of ordinary skill to provide a tube with a specific bending moment based on the intended use and function as disclosed by Makower in Col. 7, lines 4-16.

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17. **As to claim 16**, Makower teaches essentially all of the limitations except for the specifics of the wall thickness. However, it would be obvious to one of ordinary skill in the art to arrive at the particular dimensions depending on what specific medical procedure or surgical procedure the shaft member was required from since different sized tubes are used for different parts of the body when performing a surgical or medical procedure.

18. **As to claim 17**, Makower teaches a shaft member wherein the first tube is made of material selected from the group consisting of stainless steel, copper, aluminum, and brass.

19. **As to claims 18**, Makower teaches a surgical device wherein the proximal end of the shaft member is removably coupled to the handle assembly

20. **As to claim 19**, Makower teaches a surgical device wherein the distal end of the shaft member is removably coupled to the tissue engaging means.

21. **As to claim 20**, Makower teaches a surgical device further comprising an outer tube **24**, the first tube coaxially aligned and disposed within the second tube.

22. **As to claim 21**, Makower teaches a surgical device wherein the outer tube is made of material selected from the group consisting of aluminum, brass, copper and plastic.

### ***Conclusion***

23. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).



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A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mital B. Patel whose telephone number is 703-306-5444. The examiner can normally be reached on Monday-Friday (8:00 - 4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on 703-308-0101. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

mbp



Aaron J. Lewis  
Primary Examiner